

### **REMARKS**

Applicant respectfully requests reconsideration. Claims 46-71 were previously pending in this application with claims 46, 53, 59, and 65 being independent claims. The specification and claims 46-53, 59, and 65-71 have been amended. No new matter has been added.

Applicant respectfully traverses each of the rejections presented in the Office Action of September 14, 2007 for reasons similar to those set forth in prior responses of June 19, 2007, April 11, 2007, September 19, 2006, May 21, 2004 and December 23, 2003 and the declaration of Stephan N. Eldridge (hereafter the "Eldridge Declaration") submitted previously, which are incorporated herein by reference.

#### **Information Disclosure Statement**

The examiner indicated that the Woodward and Boyers references previously submitted and discussed in the prior response were not considered because they were not cited with an information disclosure statement (IDS) in compliance with 37 CFR 1.98. Without acceding to the propriety of the examiner's position, Applicant submits herewith an IDS that cites the Woodward and Boyer references. Consideration of these references is respectfully requested.

#### **Objections to the Specification**

The specification has been objected to under 35 U.S.C. §132(a) on the basis that the prior amendment to the specification introduced new matter. Applicant respectfully submits that this description is not new matter for at least the reasons set forth in the prior response of June 19, 2007. Nevertheless, without acceding to the propriety of this objection, Applicant has amended the specification to delete the purported new matter. Accordingly, the objection to the specification should be withdrawn.

#### **Rejections Under 35 U.S.C. §112**

Claims 46-71 stand rejected under 35 U.S.C. §112, first paragraph, purportedly for failing to comply with the written description requirement. The examiner contends that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed

invention at the time the application was filed. (Office Action, pages 3-4). More particularly, the examiner contends that the recitation “the barrier layer having a surface texture and a porosity less than 10 $\mu$ m” is new matter.

Applicant respectfully submits that this claim recitation is not new matter for at least the reasons set forth in the prior response of June 19, 2007. Nevertheless, without acceding to the propriety of this rejection, Applicant has amended the claims to delete the purported new matter. Accordingly, the rejection of claims 46-71 under §112, first paragraph, should be withdrawn.

### Rejections Under 35 U.S.C. §103

#### *A. Rejections in View of Mulhauser and Pease*

Claims 46, 47, 50, 54-56, 59-62, 65-68 and 71 stand rejected under 35 U.S.C. §103(a) as purportedly being unpatentable over Mulhauser (U.S. patent No. 5,695,525) in view of Pease (US 2,671,444). Applicant respectfully traverses this rejection.

Independent claims 46, 59 and 65 recite, *inter alia*, a prosthesis or repair fabric with an edge barrier that inhibits the formation of adhesions with tissue or organs thereto, wherein the edge barrier isolates or covers at least a portion of the edge of the fabric.

#### Discussion of Mulhauser

In the Office Action, the Examiner contends that Mulhauser discloses (Figs. 4a, 4b) a surgical repair material comprising a fabric 34, a barrier layer 36 and an edge barrier 32. The Examiner further contends that Mulhauser illustrates (Figs. 2a, 2b, 3h) a frame structure located at the edge to form an edge barrier.

As previously pointed out, Mulhauser ‘525 is a family member of Mulhauser ‘246 (US 5,766,246) which was previously applied during prosecution of the claims and over which the claims were found to be patentable. Applicant respectfully asserts that the claims patentably distinguish over Mulhauser ‘525 for at least the same reasons set forth in the prior responses.

Mulhauser is directed to an implantable prosthesis 10, 30 having a mesh layer 12, 34 and a semi-rigid frame or ring 14, 32 supporting the mesh layer. (Mulhauser ‘525, Col. 3, lines 42-53; col. 5, lines 24-29). In the embodiment shown in Figs. 4a-4b, the fabric extends outwardly beyond the frame or ring 32 such that the frame 32 does not cover or isolate a portion of the fabric edge. Consequently, in this particular embodiment, the frame 32 is not an edge barrier as

recited in the claims for at least this reason. Applicant does not understand the examiner's basis for continuing to assert that the frame 32 shown in Fig. 4 is an edge barrier when the fabric extends outwardly beyond the frame.

Nevertheless, as indicated in the Office Action and previously discussed, Mulhauser does disclose a prosthesis (Figs. 2) which includes a frame that covers the edge of the mesh fabric. As shown in Figs. 2 and 3(h), the frame 14 may be configured to extend over the mesh layer at both the peripheral edge of the mesh layer and the surface margin of the mesh layer adjacent the peripheral edge. However, as explained previously, Mulhauser does not teach or suggest that the frame 14, 32 has any type of adhesion inhibiting properties.

As indicated in prior responses, Applicant previously submitted a declaration to show that the Mulhauser frame does not inherently possess adhesion resistant properties. (See Eldridge Declaration). Silicone or polypropylene materials, which Mulhauser discloses may be employed for the ring or frame, do not inherently or necessarily inhibit adhesions. The adhesion resistant properties of a soft tissue repair prosthesis are affected by various factors such as the surface texture and pore size of the material that forms the prosthesis or portions of the prosthesis. (See Eldridge Declaration, paragraph 9). Thus, a prosthesis may be either resistant to the formation of adhesions or promote tissue ingrowth and adhesions depending upon the particular structural characteristics of its material. (See Eldridge Declaration, paragraph 9). For example, a prosthetic material, including silicone, having a surface texture or porosity of approximately 10 $\mu$ m or more is susceptible to adhesions with tissue or muscle. (See Eldridge Declaration, paragraph 9).

Applicant previously provided and again provides several references (Woodward, "The Tissue Response to Implants and Its Evaluation by Light Microscopy" and Boyers, "Reduction of postoperative pelvic adhesions in the rabbit with Gore-Tex surgical membrane") describing the surface texture and porosity characteristics of an implantable material as these characteristics relate to the adhesion resistance of the material. The Woodward reference (page 370, right column) discloses that surface irregularities as small as 10-15 $\mu$ m result in the development of giant cells as the principal cellular interface between the host and non-reactive implant. Thus, Woodward indicates that a material with surface irregularities of approximately 10 $\mu$ m or more is susceptible to adhesions with tissue or muscle. The Boyers reference discloses that an implant manufactured with a relatively large pore size encourages tissue attachment and the infiltration

of fibers into its microstructure, while an implant having an average pore size less than or equal to 1 $\mu$ m minimizes cellular penetration and tissue attachment. (Boyers, page 1069, left column).

Mulhauser provides no teaching or suggestion as to any structural characteristics of the frame that would determine its adhesion resistant properties. The surface texture and porosity of a silicone frame (as well as a molded polypropylene frame) can vary depending on the specific design parameters of the mold used to form the frame. (See Eldridge Declaration, paragraph 10). Therefore, a molded silicone frame can promote tissue ingrowth and adhesions with tissue and muscle. (See Eldridge Declaration, paragraph 10). Thus, although the Mulhauser frame may be molded from a silicone material, this does not necessarily provide a frame that inhibits adhesions to tissue and muscle, such that one of ordinary skill in the art would not consider the Mulhauser frame, even if formed of silicone material, as necessarily being resistant to tissue ingrowth and adhesions to tissue and muscle. (See Eldridge Declaration, paragraph 10).

In the Office Action, the Examiner again states that “the frame or edge barrier is solid or rigid to provide support to the fabric (col. 4, lines 22, 23) and thus would inhibit adhesions from forming.” (Office Action, page 3). Thus, it appears that the Examiner continues to contend that a solid or rigid frame is inherently adhesion resistant. Applicant respectfully disagrees.

Applicant respectfully asserts that nowhere does Mulhauser state that the frame is solid, although several cross-sectional views of the frame would appear to suggest that the frame is of a generally solid, as opposed to a hollow, construction. Nevertheless, as set forth in the Eldridge Declaration, nothing in the figures provide any indication that the frame is adhesion resistant. (See Eldridge Declaration, paragraph 11). As indicated above, the adhesion resistance of a material implanted in a body depends on the structural characteristics of the material, including surface texture and porosity of the material, and that tissue ingrowth can occur when the surface texture or porosity is approximately 10 $\mu$ m or more. (See Eldridge Declaration, paragraph 11). This amount of surface texture and porosity is microscopic and undetectable with the naked eye. (See Eldridge Declaration, paragraph 11). Thus, simply because the drawings in Mulhauser do not illustrate a rough surface or large pores, the drawings do not indicate that the frame is resistant to tissue ingrowth or adhesions. (See Eldridge Declaration, paragraph 11).

Moreover, a solid structure does not inherently possess adhesion resistant properties as such structures may still have a porosity and/or surface texture that allows tissue ingrowth and adhesion thereto. For example, a solid bar of chocolate typically has pores that are readily

visible to the naked eye. The Examiner has established no basis to support the contention that a “solid” or “rigid” material is inherently adhesion resistant.

As explained previously, independent claims 46, 59 and 65 require an edge barrier that “inhibits the formation of adhesions with sensitive tissue and organs thereto.” As discussed above and set forth in the Eldridge Declaration, one of ordinary skill in the art understands and would interpret this limitation as requiring the edge barrier to have particular characteristics, including porosity and surface texture characteristics, which render the barrier adhesion resistant. Mulhauser fails to disclose any particular structural characteristics for the frame, such as surface texture or porosity, that would enable one of ordinary skill in the art to conclude that the Mulhauser frame inherently inhibits the formation of adhesions thereto.

As also explained previously, the specification clearly supports the claim limitation that the peripheral barrier inhibits the formation of adhesions thereto. Further, this feature is enabled by the specification which discloses several examples of materials that are adhesion resistant.

#### Reliance on Pease to Reject the Claims

Apparently recognizing that Mulhauser fails to disclose an edge barrier having a surface texture (or a pore size) that results in preventing adhesions, the examiner looks to Pease in an attempt to cure this deficiency. In the Office Action, the examiner contends that Pease teaches (Figs. 1 and 3) an edge barrier 16 to reduce adhesions. (Office Action, page 5). The examiner also contends that Pease teaches the treatment of the material or polymer to create an inert or adhesion resistant material, citing col. 3, lines 33-39 and 57-60. (Office Action, page 5). Based on these purported teachings, the examiner concludes that it “would have been obvious to one of ordinary skill in the art to use the teachings of Pease to provide the tissue edge or contact area with adhesion resistant properties in the prosthetic repair device of Mulhauser et al. such that it does not cause any inflammation or discomfort to the patient that would result from adhesions.” (Office Action, page 5). Applicant respectfully disagrees.

#### Discussion of Pease

Pease is directed to a nonmetallic mesh for hernia repair. In particular, Pease was interested in providing a mesh implant for strengthening weak spots (i.e., a hernia) in the human body and promoting the growth of new tissue. (Col. 1, lines 1-7). Pease indicates that perhaps

the most common hernias are located at the openings in the abdominal wall through which pass the spermatic cord. (Col. 1, lines 15-17).

Pease sought to increase the percentage of successful hernia repairs by surgery and reduce the probability of recurrences by using an implantable structure that could hold the hernia and promote growth of strong fibrous tissues. (Col. 1, lines 34-41). Pease identifies several desirable properties for the implant, including biocompatibility, lack of degradation of characteristics over time, sufficient porosity for fluid drainage and tissue ingrowth, maintaining flexibility, and an ability to be trimmed without unraveling. (Col. 1, line 47 to col. 2, line 17). These properties are typically found in polypropylene mesh fabrics used for hernia repair, such as the Marlex mesh which Mulhauser identified to be the preferred fabric for use with his implantable prosthesis.

Pease also indicates that the implant should provide suitable support and protection close to the spermatic cord, or other cord structure, which passes through the implant without the likelihood of causing additional irritation or injury. (Col. 2, lines 17-23). In this regard, Pease discloses that the implant includes an opening 16 for passage of a spermatic cord through the implant. A slit 18 may be cut by the surgeon to permit entrance of the cord into the opening. (Col. 4, lines 1-5). Pease indicates that the opening is formed with a strong, smooth beaded edge that allows the cord to non-irritatingly pass through the opening. (Col. 3, lines 55-60).

As discussed further below, Pease does not teach or suggest an adhesion resistant edge barrier that inhibits the formation of adhesions with tissue and organs thereto.

*One of ordinary skill in the art would not have been led to modify Mulhauser in view of Pease.*

The alleged motivation or reason for modifying Mulhauser, presumably the frame (the Office Action identifies the “tissue edge or contact area” being modified), to have adhesion resistant properties in view of Pease finds no support in the record. In particular, Pease provides no teaching or suggestion whatsoever of any desire to provide an implant with adhesion resistant properties. To the contrary, Pease is clearly directed to an implant specifically constructed to promote tissue adhesions.

Pease teaches that the implant “must be sufficiently porous... to permit growth through itself of the fibrous tissues to form a strong solid mass.” (Col. 2, lines 1-5). Pease also states

that the “mesh-work itself promotes the ready growth therethrough of repair tissue and the insert is adapted to remain permanently in the body.” (Col. 3, lines 1-4). As one of ordinary skill in the art would appreciate, the tissue ingrowth desired by Pease results in adhesion formation to the implant.

In the Office Action, the examiner appears to suggest that Pease’s teaching of using an “inert” material implies that the structure would not promote adhesions. (Office Action, page 5). Although Pease discloses that the implant is made of a biocompatible and chemically inert material, such as polyethylene (Col. 3, lines 31-40), this does not in any way imply that the implant material is adhesion resistant. In this regard, it is well known to repair a tissue or muscle wall defect, such as a hernia, with an implantable repair mesh fabricated from “inert” materials, including the Pease mesh and the Mulhauser fabric, where the mesh allows tissue ingrowth and forms adhesions to repair a tissue defect. The fact that a material may be inert is not determinative as to whether or not it is adhesion resistant. As indicated above, the adhesion resistant properties of a soft tissue repair prosthesis are affected by various factors including the surface texture and pore size of the material that forms the prosthesis or portions of the prosthesis.

Similarly, the use of a smooth beaded edge to reduce irritations between the edge and a cord structure is also not determinative as to whether or not it is adhesion resistant. Again, the adhesion resistant properties of a material or structure are affected by the surface texture and the pore size. A smooth surface that may reduce irritation with adjacent tissue in no way implies that its surface has a texture that can also inhibit adhesion. Reducing irritations and inhibiting adhesions are not the same. Additionally, even assuming a surface or edge has a surface texture with a smoothness that both reduces irritations and inhibits adhesion formation, this does not imply that the material or structure also has a pore size that inhibits the formation of adhesions. Pease provides no teaching or suggestion as to the particular surface texture or pore size of the opening edge. Therefore, one of ordinary skill in the art would not conclude that the edge is adhesion resistant.

Even were one of ordinary skill in the art to have somehow concluded that a smooth beaded edge used to reduce irritation is inherently adhesion resistant, Applicant respectfully submits that there still would have been no apparent reason to modify Mulhauser in view of Pease. In this regard, Pease discloses using a smooth beaded edge only about an opening 16

provided in the implant for receiving the spermatic cord. Pease does not provide any indication whatsoever of a desire to employ a smooth beaded edge about its outer periphery or anywhere else, other than the opening, to reduce irritations. The Mulhauser prosthesis does not include any opening for a spermatic cord. Thus, there would have been no reason for one of skill in the art to have contemplated the use of a smooth beaded edge anywhere in the Mulhauser prosthesis, let alone the Mulhauser frame, based on the Pease teachings.

In view of the foregoing, Applicant respectfully submits that a *prima facie* case of obviousness has not been established in the office action. Mulhauser and Pease do not provide any apparent reason that would have led one of ordinary skill in the art to modify the Mulhauser frame in the manner suggested in the office action. Applicant respectfully submits that any assertion that it would have been obvious to modify Mulhauser in view of Pease would appear to be the result of improper hindsight reconstruction in view of Applicant's claimed invention. Accordingly, the rejection of independent claims 46, 59 and 65 under §103 in view of Mulhauser and Pease is improper and should be withdrawn.

*The claims patentably distinguish over Mulhauser in view of Pease.*

For the sake of argument only, even were one of ordinary skill in the art to have somehow been led to modify the Mulhauser frame to have a smooth beaded edge to reduce irritations in view of Pease, the claims patentably distinguish over the references.

As indicated above, independent claims 46, 59 and 65 recite a prosthesis or repair fabric with an edge barrier that inhibits the formation of adhesions with tissue or organs thereto, wherein the edge barrier isolates or covers at least a portion of the edge of the fabric.

As discussed above, one of ordinary skill in the art understands and would interpret this limitation as requiring the edge barrier to have particular characteristics, including porosity and surface texture characteristics, which render the barrier adhesion resistant. Mulhauser fails to disclose any particular structural characteristics for the frame, such as surface texture or porosity, that would enable one of ordinary skill in the art to conclude that the Mulhauser frame inherently inhibits the formation of adhesions thereto. Similarly, Pease fails to disclose any particular surface texture or porosity that would enable one of ordinary skill in the art to conclude that the beaded edge of the opening inherently inhibits the formation of adhesions thereto. Again, a surface construction that may reduce irritations does not necessarily inhibit adhesion formation.



Notwithstanding the foregoing, Applicant has amended claims 46, 59 and 65 to further clarify this aspect of the invention by reciting that both the barrier layer and the edge barrier are adhesion resistant and that each barrier has a pore size that discourages tissue ingrowth. This amendment is clearly supported by the original specification. (For example, see specification, page 7, lines 15-25). Claims 46 and 65 have also been amended to clarify that they are directed to an implantable prosthetic repair fabric.

In view of the foregoing, claims 46, 59 and 65 patentably distinguish over Mulhauser and Pease, taken either alone or together, which fail to teach or suggest an adhesion resistant edge barrier that inhibits the formation of adhesions with tissue or organs thereto, where the edge barrier has a pore size that discourages tissue ingrowth. Thus, the rejection of claims 46, 49 and 65 under §103 should be withdrawn for at least this additional reason.

Claims 47 and 50, claims 60-62, and claims 66-68 and 71 respectively depend from claims 46, 59 and 65 and are patentable for at least the same reasons. It is unclear as to the basis for the rejection of claims 54-56 as they depend from claim 53 which has not been rejected in view of Mulhauser and Pease. Nevertheless, claim 53, which also recites an edge barrier as discussed further below, patentably distinguishes over Mulhauser and Pease for at least the same reasons as independent claims 46, 59 and 65, and claims 54-56 are patentable for at least the same reasons. Accordingly, withdrawal of these rejections is respectfully requested.

*B. Rejections in View of Meier and Pease*

Claims 53, 56, 65, 68 and 71 stand rejected under 35 U.S.C. §103(s) as purportedly being unpatentable over Meier (U.S. patent No. 3,416,524) in view of Pease. Applicant respectfully traverses these rejections.

Independent claim 65 is discussed above.

Independent claim 53 recites, *inter alia*, an implantable prosthesis comprising a repair fabric and an edge barrier that inhibits the formation of adhesions with tissue or organs thereto, wherein the edge barrier covers at least a portion of the edge of the fabric.

*Discussion of Meier*

Meier is directed to a non-adherent surgical dressing including a laminated pad 13 with a cellulosic layer 14 and a resin fiber layer 15 which are joined by needled resin fibers 16 using a

needling and heat fusion process. The cellulosic layer has moisture absorption properties while the resin fiber layer has a porous surface which serves as the non-adherent contact surface for the wound and which permits free flow to moisture. The pad is surrounded by an edge frame or crown 12 which stabilizes the edges of the cellulosic layer and the resin fiber layer.

Meier does not teach or suggest that the frame, which the examiner identifies as an edge barrier, has any type of adhesion inhibiting properties. Rather, Meier merely discloses that frame provides freedom from fraying, loose fibers, delamination and the like by surrounding and stabilizing the edges of the cellulosic layer and the resin fiber layer. (Col. 2, lines 51-56). Meier indicates that the frame may be fabricated from any of a variety of materials, such as an inert thermoplastic substance, which is sufficiently flexible for purposes of being applied with the pad to curved body surfaces and yet which affords sufficient rigidity to stabilize the pad and prevent delamination, etc. (Col. 2, line 67 to Col. 3, line 2).

In the office action, the examiner states that the frame would inhibit adhesions because it is made of an inert material. (Office Action, page 6). Applicant respectfully disagrees.

Although Meier discloses that the frame may be made of an inert thermoplastic material such as polypropylene (Col. 2, line 69 to col. 3, line 3), this does not in any way imply that the frame would inhibit adhesions, as asserted by the examiner. As explained above, it is well known to repair a tissue or muscle wall defect, such as a hernia, with an implantable repair mesh fabricated from polypropylene monofilament, an inert material, where the mesh allows tissue ingrowth and forms adhesions to repair a tissue defect. The fact that a material may be inert is not determinative as to whether or not it is adhesion resistant. Again, the adhesion resistant properties of a soft tissue repair prosthesis are affected by various factors including the surface texture and pore size of the material that forms the prosthesis or portions of the prosthesis. Thus, a prosthesis may be either resistant to the formation of adhesions or promote tissue ingrowth and adhesions depending upon the particular structural characteristics of its material. For example, as discussed above, one of ordinary skill in the art understands that a prosthetic material having a surface texture or porosity of approximately 10 $\mu$ m or more is not adhesion resistant, but rather is susceptible to adhesions with tissue or muscle.

As explained previously, Meier provides no teaching or suggestion as to any structural characteristics of the frame that would allow one of ordinary skill in the art to determine its adhesion resistant properties. Although Meier discloses that the frame may be formed from any

of various materials, Meier is silent as to the structural characteristics, such as surface texture and porosity, that affect its adhesion resistance, such that one of ordinary skill in the art would not consider the Meier frame as necessarily being resistant to tissue ingrowth and adhesions to tissue and muscle. Thus, Meier does not disclose at least an edge barrier that inhibits the formation of adhesions with tissue and organs thereto.

*Reliance on Pease to Reject the Claims*

Apparently recognizing that Meier fails to disclose an edge barrier having a surface texture or a pore size that results in preventing adhesions, the examiner looks to Pease in an attempt to cure this deficiency. Pease is discussed above.

Based on the purported teachings of Pease, the examiner concludes that it “would have been obvious to one of ordinary skill in the art to use the teachings of Pease to provide the tissue edge or contact area with adhesion resistant properties in the prosthetic repair device of Meier such that it does not cause any inflammation or discomfort to the patient that would result from adhesions.” (Office Action, page 6). Applicant respectfully disagrees.

*One of ordinary skill in the art would not have been led to modify Meier in view of Pease.*

The alleged motivation or reason for modifying Meier, presumably the frame (the Office Action identifies the “tissue edge or contact area” being modified), to have adhesion resistant properties in view of Pease finds no support in the record. As explained above, Pease provides no teaching or suggestion whatsoever of any desire to provide an implant with adhesion resistant properties. To the contrary, Pease is clearly directed to an implant specifically constructed to promote tissue adhesions. In this regard, as discussed above, one of ordinary skill in the art would appreciate that the tissue ingrowth desired by Pease results in adhesion formation to the implant.

As explained above, the fact that a material may be inert is not determinative as to whether or not it is adhesion resistant. Similarly, the use of a smooth beaded edge to reduce irritations between the edge and a cord structure is also not determinative as to whether or not it is adhesion resistant. Again, Pease provides no teaching or suggestion as to the particular surface texture or pore size of the opening edge that would lead one of ordinary skill in the art to conclude that the edge is adhesion resistant.

Even were one of ordinary skill in the art to have somehow concluded that a smooth beaded edge used to reduce irritation is inherently adhesion resistant, Applicant respectfully submits that there still would have been no apparent reason to modify Meier in view of Pease. As discussed above, Pease discloses using a smooth beaded edge only about an opening 16 provided in the implant for receiving the spermatic cord. Pease does not provide any indication whatsoever of a desire to employ a smooth beaded edge about its outer periphery or anywhere else, other than the opening, to reduce irritations. The Meier dressing does not include any opening for a spermatic cord. Thus, there would have been no reason for one of skill in the art to have contemplated the use of a smooth beaded edge anywhere in the Meier dressing, let alone the Meier frame, based on the Pease teachings. Additionally, the Meier dressing is not an implantable prosthesis for repairing a hernia, such that there would have been no reason to provide, or even contemplate providing, such an opening in the device.

In view of the foregoing, Applicant respectfully submits that a *prima facie* case of obviousness has not been established in the office action. Meier and Pease do not provide any apparent reason that would have led one of ordinary skill in the art to modify the Meier frame in the manner suggested in the office action. Applicant respectfully submits that any assertion that it would have been obvious to modify Meier in view of Pease would appear to be the result of improper hindsight reconstruction in view of Applicant's claimed invention. Accordingly, the rejection of independent claims 53 and 65 under §103 in view of Meier and Pease is improper and should be withdrawn.

*The claims patentably distinguish over Meier in view of Pease.*

For the sake of argument only, even were one of ordinary skill in the art to have somehow been led to modify the Meier frame to have a smooth beaded edge to reduce irritations in view of Pease, the claims patentably distinguish over the references.

As indicated above, independent claims 53 and 65 are directed to an implantable prosthesis. In contrast, Meier is directed to a surgical dressing, not an implantable prosthesis as contended in the office action. Meier provides no teaching or suggestion that the surgical dressing can be or is even capable of being used as an implantable prosthesis. Thus, independent claims 53 and 65 patentably distinguish over the modification of Meier in view of Pease such

that the rejection of claims 53 and 65 under §103 should be withdrawn for at least this additional reason.

As indicated above, independent claims 53 and 65 also recite a prosthesis or repair fabric with an edge barrier that inhibits the formation of adhesions with tissue or organs thereto, wherein the edge barrier isolates or covers at least a portion of the edge of the fabric.

As discussed above, one of ordinary skill in the art understands and would interpret this limitation as requiring the edge barrier to have particular characteristics, including porosity and surface texture characteristics, which render the barrier adhesion resistant. Meier fails to disclose any particular structural characteristics for the frame, such as surface texture or porosity, that would enable one of ordinary skill in the art to conclude that the Meier frame inherently inhibits the formation of adhesions thereto. Similarly, Pease fails to disclose any particular surface texture or porosity that would enable one of ordinary skill in the art to conclude that the beaded edge inherently inhibits the formation of adhesions thereto. Again, a surface construction that may reduce irritations does not necessarily inhibit adhesion formation.

Notwithstanding the foregoing, Applicant has amended claim 53 (and claim 65 as discussed above) to further clarify this aspect of the invention by reciting that both the barrier layer and the edge barrier are adhesion resistant and that each barrier has a pore size that discourages tissue ingrowth. As indicated above, this amendment is clearly supported by the original specification. (For example, see specification, page 7, lines 15-25).

In view of the foregoing, claims 53 and 65 patentably distinguish over Meier and Pease, taken either alone or together, which fail to teach or suggest an adhesion resistant edge barrier that inhibits the formation of adhesions with tissue or organs thereto, where the edge barrier has a pore size that discourages tissue ingrowth. Thus, the rejection of claims 53 and 65 under §103 should be withdrawn for at least this additional reason.

Claim 56 and claims 68 and 71 respectively depend from claims 53 and 65 and are patentable for at least the same reasons.

*C. Rejections in View of Mulhauser, Pease and Gianturco*

Claims 48, 49, 51, 52, 57, 58, 63, 64, 69 and 70 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Mulhauser '525 in view of Pease, and further in view of Gianturco (US 5,258,000). Applicant respectfully traverses these rejections.


Without acceding to the propriety of the combination as suggested by the Examiner, claims 48, 49, 51 and 52 depend from claim 46 and are patentable for at least the same reasons set forth above. Similarly, claims 57 and 58 depend from claim 53 and are patentable for at least the same reasons set forth above; claims 63 and 64 depend from claim 59 and are patentable for at least the same reasons set forth above; and claims 69 and 70 depend from claim 65 and are patentable for at least the same reasons set forth above. Accordingly, withdrawal of these rejections is respectfully requested.

### CONCLUSION

In view of the foregoing remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the undersigned attorney at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,

By:   
James M. Hanifin, Jr., Reg. No. 39,213  
WOLF, GREENFIELD & SACKS, P.C.  
600 Atlantic Avenue  
Boston, Massachusetts 02210-2211  
Telephone: (617) 720-3500

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